(2) The facility files a request to retain the rate with its fiscal intermediary during the 30-day period before the opening of an exception cycle; and

(3) The request is approved by the fiscal intermediary.

(f) *Documentation for a payment rate exception request.* If the facility is requesting an exception to its payment rate, it must submit to HCFA its most recently completed cost report as required under § 413.198 and whatever statistics, data, and budgetary projections as determined by HCFA to be needed to adjudicate each type of exception. HCFA may audit any cost report or other information submitted. The materials submitted to HCFA must—

(1) Separately identify elements of cost contributing to costs per treatment in excess of the facility's payment rate;

(2) Show that the facility's costs, including those costs that are not directly attributable to the exception criteria, are allowable and reasonable under the reasonable cost principles set forth in this part;

(3) Show that the elements of excessive cost are specifically attributable to one or more conditions specified in § 413.182;

(4) Specify the amount of additional payment per treatment the facility believes is required for it to recover its justifiable excess costs; and

(5) Specify that the facility has compared its most recently completed cost report with cost reports from (at least 2) prior years. The facility must explain any material statistical data or cost changes, or both, and include an explanation with the documentation supporting the exception request.

(g) *Completion of requirements and criteria.* The facility must demonstrate to HCFA's satisfaction that the requirements of this section and the criteria in § 413.182 are fully met. The burden of proof is on the facility to show that one or more of the criteria are met and that the excessive costs are justifiable under the reasonable cost principles set forth in this part.

(h) *Approval of an exception request.* An exception request is deemed approved unless it is disapproved within 60 working days after it is filed with its intermediary.

(i) *Determination of an exception request.* In determining the facility's payment rate under the exception process, HCFA excludes all costs that are not reasonable or allowable under the reasonable cost principles set forth in this part.

(j) *Period of approval: Payment exception request.* Except for exceptions approved under §§ 413.180(e), 413.180(k), 413.182(c), and 413.188, a prospective exception payment rate approved by HCFA applies for the period from the date the complete exception request was filed with its intermediary until the earlier of the—

(1) Date the circumstances justifying the exception rate no longer exist; or

(2) End of the period during which the announced rate was to apply.

(k) *Period of approval: Payment exception request under §§ 413.182(c) and 413.188.* A prospective exception payment rate approved by HCFA under §§ 413.182(c) and 413.188 applies from the date of the extraordinary event until the end of the period during which the prospective announced rate was to apply, unless HCFA determines that another date is more appropriate. If HCFA does not extend the exception period and the facility believes that it continues to require an exception to its rate, the facility must reapply in accordance with the procedures in this section.

(l) *Denial of an exception request.* HCFA denies exception requests submitted without the documentation specified in § 413.182 and the applicable regulations cited there.

(m) *Criteria for refiling a denied exception request.* A facility that has been denied an exception request during the 180 days may file another exception request if all required documentation is filed with the intermediary by the 180th day.

§ 413.182 Criteria for approval of exception requests.

HCFA may approve exceptions to an ESRD facility's prospective payment rate if the facility demonstrates, by convincing objective evidence, that its total per treatment costs are reasonable and allowable under the relevant

cost reimbursement principles of part 413 and that its per treatment costs in excess of its payment rate are directly attributable to any of the following criteria:

(a) Atypical service intensity (patient mix), as specified in § 413.184.

(b) Isolated essential facility, as specified in § 413.186.

(c) Extraordinary circumstances, as specified in § 413.188.

(d) Self-dialysis training costs, as specified in § 413.190.

(e) Frequency of dialysis, as specified in § 413.192.

§ 413.184 Payment exception: Atypical service intensity (patient mix).

(a) To qualify for an exception to the prospective payment rate based on atypical service intensity (patient mix)—

(1) A facility must demonstrate that a substantial proportion of the facility's outpatient maintenance dialysis treatments involve atypically intense dialysis services, special dialysis procedures, or supplies that are medically necessary to meet special medical needs of the facility's patients. Examples that may qualify under this criterion are more intense dialysis services that are medically necessary for patients such as—

(i) Patients who have been referred from other facilities on a temporary basis for more intense care during a period of medical instability and who return to the original facility after stabilization;

(ii) Pediatric patients who require a significantly higher staff-to-patient ratio than typical adult patients; or

(iii) Patients with medical conditions that are not commonly treated by ESRD facilities and that complicate the dialysis procedure.

(2) The facility must demonstrate clearly that these services, procedures, or supplies and its per treatment costs are prudent and reasonable when compared to those of facilities with a similar patient mix.

(3) A facility must demonstrate that—

(i) Its nursing personnel costs have been allocated properly between each mode of care; and

(ii) The additional nursing hours per treatment are not the result of an excess number of employees.

(b) *Documentation.* (1) A facility must submit a listing of all outpatient dialysis patients (including all home patients) treated during the most recently completed fiscal or calendar year showing—

(i) Patients who received transplants, including the date of transplant;

(ii) Patients awaiting a transplant who are medically able, have given consent, and are on an active transplant list, and projected transplants;

(iii) Home patients;

(iv) In-facility patients, staff-assisted, or self-dialysis;

(v) Individual patient diagnosis;

(vi) Diabetic patients;

(vii) Patients isolated because of contagious disease;

(viii) Age of patients;

(ix) Mortality rate, by age and diagnosis;

(x) Number of patient transfers, reasons for transfers, and any related information; and

(xi) Total number of hospital admissions for the facility's patients, reason for, and length of stay of each session.

(2) The facility also must—

(i) Submit documentation on costs of nursing personnel (registered nurses, licensed practical nurses, technicians, and aides) incurred during the most recently completed fiscal year cost report showing—

(A) Amount each employee was paid;

(B) Number of personnel;

(C) Amount of time spent in the dialysis unit; and

(D) Staff-to-patient ratio based on total hours, with an analysis of productive and nonproductive hours.

(ii) Submit documentation on supply costs incurred during the most recently completed fiscal or calendar year cost report showing—

(A) By modality, a complete list of supplies used routinely in a dialysis treatment;

(B) The make and model number of each dialyzer and its component cost; and

(C) That supplies are prudently purchased (for example, that bulk discounts are used when available).